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forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

20. The method of using a combination catheter as set forth in claim 19 further including the step of positioning the combination catheter in a desired position, and using the combination catheter in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane.

21. The method of using a combination catheter as set forth in claim 20 further including the step of reforming the distal end of the combination catheter into a substantially different shape.

22. The method of using a combination catheter as set forth in claim 21 further including the step of using the combination catheter in a medical procedure while the distal end of the combination catheter is in the reformed shape.

REMARKS

The Examiner has rejected claims 8 and 17 because of the presence of the phrase "mathematically rotating". Those claims are cancelled herewith, so this rejection is now moot. With respect to claims 14 and 16, the Examiner has questioned whether "separated in operation" is a positive recitation. Both claims are amended to even more positively recite the operation. That objection is also, therefore, moot.

The Examiner in his Section 112 rejection also takes the position that "An axis is a straight line." That is not true, particularly in the current context. Claim 1, for example, claims "a catheter tube having a distal end portion fixed in a first curve **such that the longitudinal axis of the distal end portion of the catheter tube defines a first plane".** Since the longitudinal

axis "defines a first plane" it cannot be a straight line (an infinite number of planes pass through a straight line). Moreover, U.S. Patent 6,309,374 (for example) states: "As can be seen in FIG. 3b, **the longitudinal axis** 78 of needle 27 **is curved** to preferably correspond to the ***curved axis*** of the curved channel 22. Needle 26 is movable along the **curved longitudinal axis** 78." Usage in this art and in the present application clearly shows that a longitudinal axis need not be straight. Such usage in medicine is not uncommon. For example, "axis" as used in anatomy refers to "any of several axial parts; especially, the spinal column." Webster's New Universal Unabridged Dictionary (2d. ed. 1983). Note that various other axes may also be curved, such as (1) an "axis of symmetry of a body"—the line on both or all sides of which the parts of a body are symmetrically arranged, and (2) "spiral axis"—in architecture, the axis of a twisted column or shaft drawn spirally so that the circumvolutions may be traced externally. (Both definitions from Webster's New Universal Unabridged Dictionary (2d. ed. 1983)).

The claims of this application are directed to what applicant refers to as his "out-of-plane" invention. Claim 1, for example, provides for a combination catheter such as the catheter shown in Fig. 15 of the present application (reproduced below) having a catheter tube 33 and an inner medical element 35. Fig. 15 is an elevation in which the inner medical element 35 is coming out of the plane of the paper. Fig. 15A is a top plan view in which "P" is the plane of the paper in Fig. 15 and inner medical element 35 is clearly illustrated as coming out of the plane P. Fig. 15B is a perspective line drawing showing various out-of-plane shapes achievable by the present invention. It should be appreciated that out-of-plane shapes are useful not because they point in particular directions (a simpler shape pointing in the same direction can always be found), but because those shapes provide an "anchoring" or "wedging" effect that maintains the

combination catheter in a desired position in the body. As will appear, the prior art cited against these "out-of-plane" claims are directed to **aiming, not shaping**.

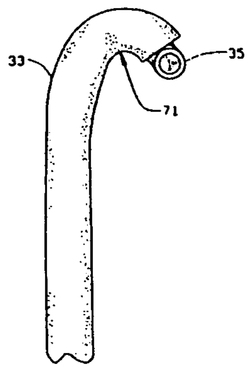


FIG. 15

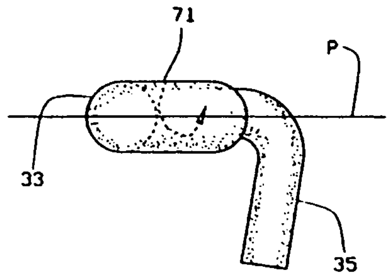


FIG. 15A

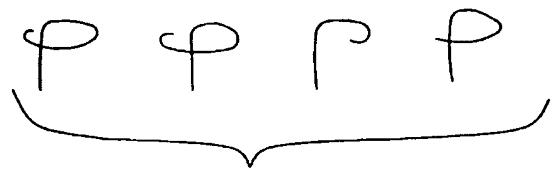


FIG. 15B

Front Elevation **Top Plan** **Line Drawings of Out-of-Plane Shapes**

The catheter tube 33 is specified as having a distal end portion fixed in a first curve such that the longitudinal axis of the distal end portion of the catheter tube defines a first plane. The first plane P is illustrated in Fig. 15A of the present application, above. Note that the longitudinal axis of the distal end portion of catheter tube 33 is disposed in plane P, while the distal portion of inner element 35 is disposed substantially out of plane P.

The inner medical element 35 is specified as having a distal end portion (the distal end portion of the inner medical element is illustrated in Fig. 15A) fixed in a second curve. The longitudinal axis of the distal end portion of the inner medical element is specified as being disposed substantially out of the first plane.

Models illustrating the various families of curves achievable with the present invention were sent to the Examiner in connection with the parent application. Such models will greatly facilitate understanding of the issues, as will the videotape supplied at the same time to the Examiner, demonstrating a computerized simulation of the use of the models. Models and the

videotape are believed to be currently in the Examiner's possession, as a result of the prosecution of the parent case. Applicant respectfully requests the opportunity to interview this case for the purpose of demonstrating the models and showing the videotape.

The Examiner has rejected claim 1 over Sylvanowicz under § 102(e) or § 103. This rejection is not well-founded. Claim 1 clearly requires that the "distal end portion" of the catheter tube assume and maintain a curved configuration. As the drawings from Sylvanowicz clearly show and the specification explicitly states (col. 6, lines 55-56), the distal end portion 62 of catheter tube 52 in Sylvanowicz is **straight** not curved. The Examiner erroneously frees himself from this limitation by selecting some other arbitrary portion of the Sylvanowicz catheter tube which is curved. The Examiner, in moving proximally along the Sylvanowicz catheter to include the curved portion, takes the catheter outside the scope of the present claims. Claim 1 provides that the distal end portion of the catheter tube is "fixed in a first curve." The present application reveals that "fixed" in this context means either (1) preformed in a curved shape, or (2) bent into a curved shape by a pull-wire. The curved portion of Sylvanowicz is not "fixed" in either of these senses. The portion of the catheter tube in Sylvanowicz shown as curved is not fixed—rather it is free to assume the shape of whatever vessel it occupies.

Moreover, the Examiner appears to be taking the position that the drawings of Sylvanowicz (that show that Sylvanowicz catheter tube to be in a single plane) is not accurate because the relationship along the aortic arch is not, in fact, planar. If the aortic arch is not planar, then the curved tube of Sylvanowicz disposed in that arch does not inherently have a longitudinal axis that defines a single plane—the longitudinal axis of the Sylvanowicz tube extending over the arch may lie in many different planes. In that case, the present claim does not read on the Sylvanowicz art, and that art is not invalidating. In this case, the portion of the

catheter tube of Sylvanowicz selected by the Examiner does not inherently define a first plane as required by these claims. On the other hand, the aortic arch could be large enough to allow the longitudinal axes of the inner and outer tubes of Sylvanowicz to be planar in the Fig. 12 position (see below) and in the Fig. 14 position (also shown below), although those two planes would not coincide. But even in this case, neither the Fig. 12 nor the Fig. 14 configuration of Sylvanowicz would anticipate the present claim which requires an "out-of-plane" shape during medical use of the inner medical element or the catheter tube. This is simply not shown in or inherent in Sylvanowicz.

The Examiner takes the position that the "out-of-plane" feature of certain of the claims is inherently present in the cited art, specifically Sylvanowicz. This conclusion cannot be true, as shown by the Examiner's actions in one of the parent applications of the present application. In application Serial No. 07/834,007, the Examiner refused to accept new drawings showing the out-of-plane feature stating:

> "The curves that are generated as shown in new figures 13-15B would not necessarily be expected based upon the original disclosure." (p. 2 of Office action dated 11/19/92).

If this was true of applicant's disclosure at the time, it is certainly true of Sylvanowicz. Sylvanowicz simply does not teach the out-of-plane feature of claim 1.

With respect to inherency, it should be noted that

> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.' *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1368, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). 'Inherency, however,

may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' *Id.* at 1269, 20 USPQ2d at 1749."

In re Robertson, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). As will be shown, the Examiner has shown a possibility that Sylvanowicz has this feature. Certainly there is no showing (1) that the out of plane feature is "necessarily present" in Sylvanowicz, or that (2) "it would be so recognized by persons of ordinary skill in the art."

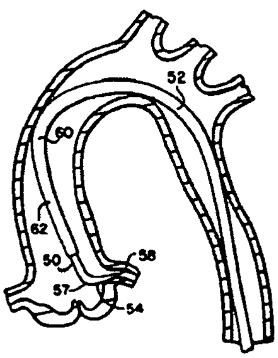


Fig. 12

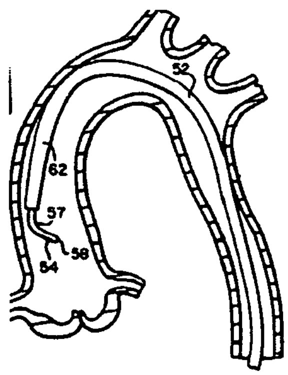


Fig. 13

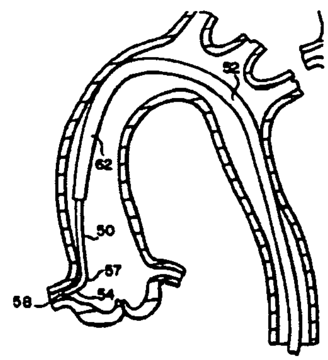


Fig. 14

The Examiner also asserts that in moving the Sylvanowicz catheter from the figure 12 position to the figure 14 position it must inherently pass through an out of plane configuration. But this approach ignores a fundamental limitation of the claim. Claim 1 clearly requires that the "distal end portion" of the catheter tube assume and maintain a curved configuration. As the above drawings from Sylvanowicz clearly show, the distal end portion 62 of catheter tube 52 in Sylvanowicz is straight in Fig. 12 and in Fig. 14, and there is no indication that the distal end portion 62 is curved at any time in moving from the Fig. 12 position to the Fig. 14 position. In fact, Sylvanowicz specifically identifies portion 62 as "**straight** distal segment 62 extending from the curved portion 60." (col. 6, ll. 55-56)(Emphasis added). Since the distal end portion of

the catheter tube in Sylvanowicz is straight, it is incapable of providing the surprising interaction of two curves which results in the inner element being thrown out of plane with respect to the outer catheter tube.

The Examiner takes the position that in moving from the Fig. 12 to the Fig. 14 position, the catheter must go out-of-plane. But that conclusion is false. The present claims clearly define the plane with respect to the longitudinal axis of the **curved distal end portion** of the outer catheter, not with respect to the outer catheter as a whole. It is only by ignoring the plain language of the claim and of Sylvanowicz ("**straight** distal segment 62") that the Examiner is able to reach his erroneous conclusion as to what must happen.

This difference between Sylvanowicz and the presently claimed invention is seen more clearly by examining the following figures from the present application.

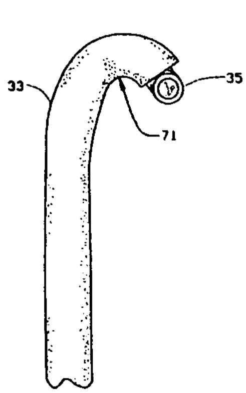


FIG. 15

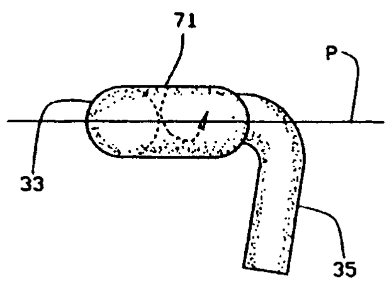


FIG. 15A

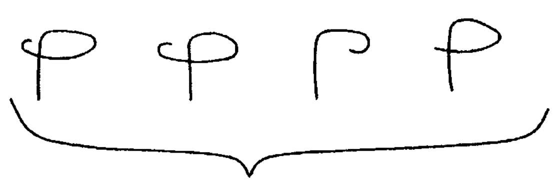


FIG. 15B

In Fig. 15 of the present application, the distal end portion of the catheter tube is clearly curved in the plane of the paper and the inner curved element, as a result, has its distal end portion thrown out of the plane of the paper (as shown in Fig. 15A). The two curves (that of the longitudinal axis of the curved distal end portion of the catheter tube and that of the longitudinal axis of the

curved distal end portion of the inner element) are in two different planes, which provides an overall out-of-plane shape as illustrated in Fig. 15B.

Contrast this with Sylvanowicz in which a single plane always contains the longitudinal axis of the straight distal end portion 62 of the catheter tube and the longitudinal axis of the distal end portion 54 of the inner element, **even as the inner element is rotated from one position to the next**. The result is different in Sylvanowicz because the distal end portion 62 of the catheter tube is straight, not curved as required by the present claim. An infinite number of planes pass through the longitudinal axis of the straight distal end portion 62 of the catheter tube in Sylvanowicz, and so in the Fig. 12 and Fig. 14 positions in Sylvanowicz and in all positions in between, the longitudinal axis of the distal end portion 54 of the inner element lies in one of those planes.

Note that, as explained above, there is no assurance (under the Examiner's assumptions) that the curved portion of the outer catheter tube in Sylvanowicz lies in the same plane as the straight distal end portion 62, or in fact that it lies in a single plane at all. Sylvanowicz, therefore, whether considered properly (with a straight distal end portion 62) or considered expansively, neither shows nor suggests the invention of claim 1.

In addition, it should be noted that claim 1 specifically requires that the second plane (the plane defined by the longitudinal axis of the distal end portion of the inner element) be "substantially out of the first plane" (the plane of the longitudinal axis of the <u>distal end portion</u> of the catheter tube). Nothing in Sylvanowicz even hints at this feature. The distal end portions in Sylvanowicz (when properly construed) always seem to be in substantially the same plane, in contrast to the requirement of claim 1. The drawings indicate that is so, and there is no showing that those portions in Sylvanowicz are <u>necessarily</u> in planes <u>at significant angles</u> with respect to

each other, or that anyone in the art has ever recognized the presently claimed "out of plane" feature. Moreover, no one has recognized the huge advantages of being able to obtain this entire family of "out of plane" shapes from two curvable elements. In fact, such a construction is immensely useful. It permits two planar elements (the inner element and the outer tube) to interact to provide an out-of-plane position for the distal end. It should be recognized that out-of-plane positioning is extremely useful in the human body. Yet Sylvanowicz fails to even hint at this feature.

The Examiner also seems to be taking the position that transitorily the plane of the distal end of the inner element in Sylvanowicz must be out of the plane of the outer tube in moving 180 degrees with respect to the outer tube. This is not correct, as explained above, because the proper portion of the outer tube in Sylvanowicz is straight, not curved. Moreover, claim 1 has been amended to provide that the relative positions of the inner and outer elements are to be measured "during a period of time sufficient to permit medical use of" either the inner medical element or the catheter tube. This language clearly excludes the transitory configuration hypothesized by the Examiner.

Claims 2-7 depend from claim 1 and are allowable therewith.

Claim 2 further provides that the inner medical element is fixed rotationally with respect to the catheter tube. The Examiner considers this feature to be inherent in Sylvanowicz since Sylvanowicz discloses a fitting which provides a fluid seal between the catheter tube and the inner element. In fact, Sylvanowicz clearly contemplates rotation of the inner tube with respect to the outer. Apparatus that is designed to rotate can hardly be said to be "fixed" against rotation. Thus, Sylvanowicz teaches directly away from the invention of claim 2.

Claim 5 further provides that the curves in the inner element and the catheter tube both must be disposed from the ends of their respective elements a distance "not substantially greater than three times the smaller" of the radii of curvature of the two curves. The only curve in the outer catheter tube of the Sylvanowicz reference is disposed substantially farther from the distal end of the catheter tube than three times the radius of the curve of the inner element (which is the curve with the smaller radius of curvature). This feature is impossible to find in the Sylvanowicz reference. This same feature is described in claim 7 in terms of the arc lengths of the various curves. It too is absent from Sylvanowicz.

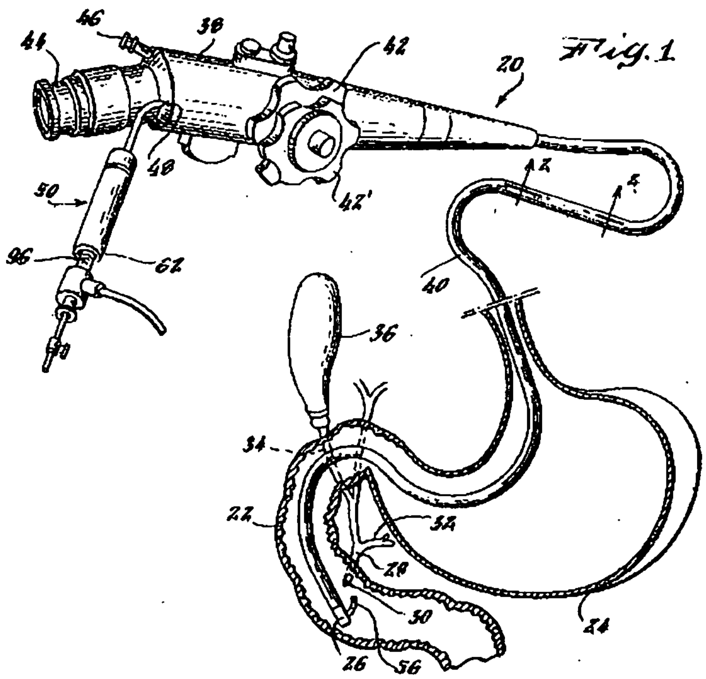
Claim 10 is a method claim that includes the various elements from claim 1 described above as missing from Sylvanowicz. It also includes the requirement that the inner element is fixed in the out-of-plane configuration for a period of time sufficient to permit medical use of either the inner element or the catheter tube. This requirement necessarily excludes the "transitory" shape theory of the Examiner discussed above. Claim 10 is allowable for all these reasons.

Claims 11-16 depend from claim 10 and are allowable therewith.

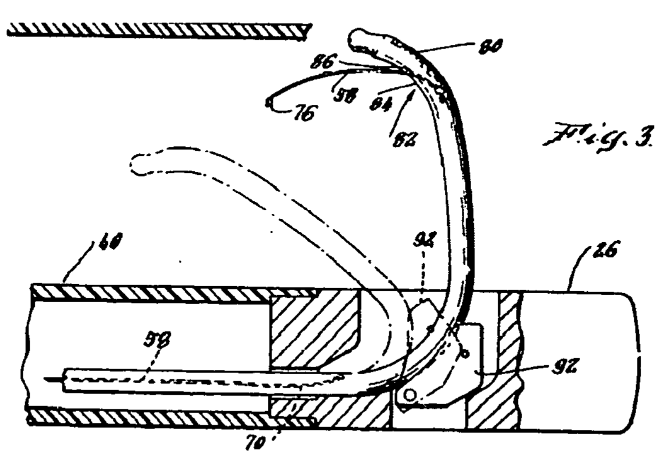
In addition, claim 11 provides that the inner medical element is fixed rotationally with respect to the catheter tube. As explained above, this feature is absent from Sylvanowicz. Similarly, claims 14 and 16 are amended herewith to include the feature defining the distance of the curves from the distal end of the respective elements, a feature that (as explained above) is totally absent from Sylvanowicz.

For all these reasons, claims 1-3, 5, 7, 10-12, 14 and 16 are allowable.

The Examiner has rejected claims 1-18 under Section 102(b) as anticipated by Petruzzi, or alternatively, under Section 103(a) over Petruzzi alone or in combination with Cho. Petruzzi can best be understood from an examination of its drawings. Fig. 1 is set forth below:



As can clearly be seen in this drawing, Petruzzi has a straight distal portion of the outer tube whose longitudinal axis is in the same plane as the distal portion of a curved inner element 56. As shown in Fig. 3, below, the inner element can be extended out through an opening in the side of endoscope 40 and its angle may be changed by means of a movable wedge 92.



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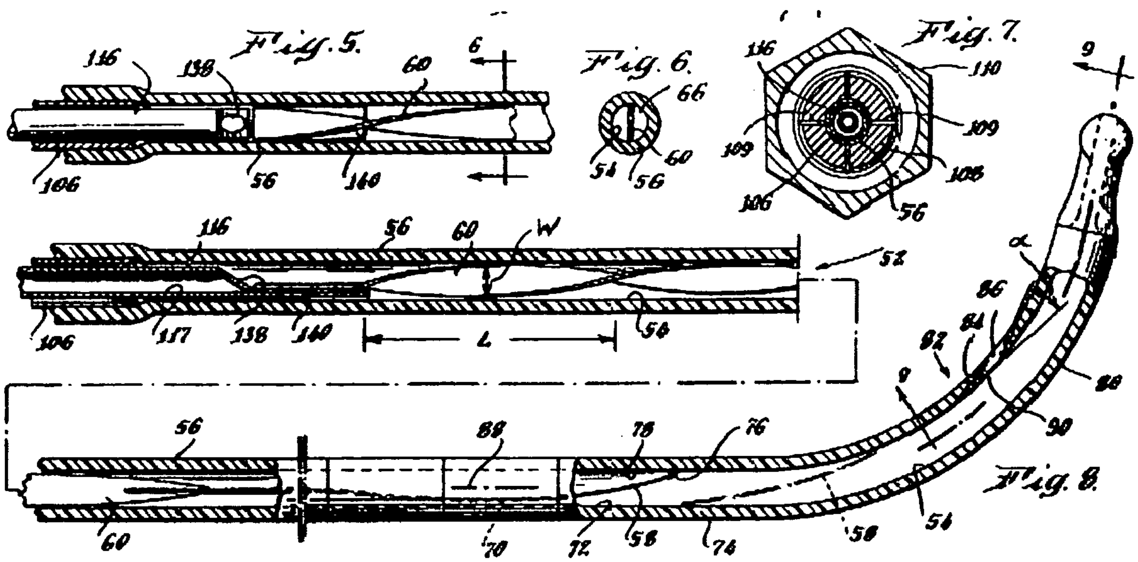


Curved element 56 and a tool 58 contained therein are shown in more detail in Fig. 8 from Petruzzi. Note that there is no indication the inner element 56 in Petruzzi will occupy any plane other than the one defined by the longitudinal axis of the outer tube. In fact, in Fig. 1 of Petruzzi the window or opening in the endoscope (shown but not labeled in Fig. 3 above) through which member 56 extends cannot be seen, thereby indicating that the plane defined by the distal end portion of outer element is not in the plane of the paper, but rather is in some other plane—presumably the one including element 56 and a valve 30 known as the ampulla of Vater.

The drawings of Petruzzi, which hide the opening facing the ampulla of Vater, are totally consistent with a manipulation which result in the distal end, the window, and the guiding catheter of Petruzzi being "in plane", not out-of-plane as required by these claims. Moreover, an out-of-plane shape of the distal end in Petruzzi, as explained below, is unachievable since the distal end is straight, solid, and unbendable. With the apparatus of Petruzzi, the only way to direct the catheter to the ampulla of Vater is by seeing the ampulla straight on line of sight through the window. This is a matter of basic physics. If the window of the endoscope were positioned in a left/right manner as theorized by the Examiner, the medial wall (and not the

posterior wall containing the ampulla) would be visualized. In that case, since the ampulla would not be in sight, it could not be catheterized. In fact, one does not see the window in Fig. 1 of Petruzzi, which is totally consistent with the window and the optics facing the ampulla in the posterior wall—allowing the catheter to be extended *in the plane* of the window and ampulla so that all elements are clearly in a single plane. With the Petruzzi device, unless the object (in this case the ampulla of Vater) is in line of sight view, it cannot be catheterized. The Examiner's theory of events—looking in one direction and catheterizing in another which you cannot see and do not know the location of—is impossible with the Petruzzi device. Petruzzi *could* show many things, but it does not show or suggest this invention.

The Petruzzi rejection is apparently based upon inherency. The Examiner states: "It would also seem inherent that both the inner catheter as well as the instrument of Petruzzi are rotatable about the longitudinal axis and done in an out of plane manner since such would facilitate the access of the various body lumens." This theory is fatally flawed—as explained above, Petruzzi simply does not and will not work in that manner. These statements of the Examiner clearly do not meet the Federal Circuit test for inherency set forth above. Claim 1 requires that the curved distal end portion of the catheter tube have a longitudinal axis that is disposed substantially in a first plane. It also requires a curved distal end portion of the inner medical element whose longitudinal axis is substantially disposed in the second plane. Nothing in Petruzzi comes close to hinting that these distal end portions of the two parts could be disposed "at a significant angle" with respect to each other. Instead, it appears that in Petruzzi these distal end portions are "substantially planar." There is a teaching of this feature and an incentive to make it, but that teaching and incentive lie in the present invention, not in the prior art.

Does the "distal end portion" of the outer tube in Petruzzi assume and maintain a curved configuration so that the longitudinal axis of the distal end portion is fixed in a first plane? That is certainly not shown in the drawings, and from Petruzzi is it difficult to see how it could be true. As can be seen in Fig. 3 of Petruzzi, the distal end of the outer tube is solid and straight. Moreover, there is absolutely no mechanism for bending the distal end of Petruzzi, again as shown in Fig. 3. Like Sylvanowicz, Petruzzi lacks any suggestion of the interaction of two curved elements which results in the surprising "out of plane" feature of claim 1.

As discussed above, claims 2-7 depend from claim 1 and are allowable therewith. None of the features discussed above as absent from Sylvanowicz are found in Petruzzi. These claims are allowable for the same reasons set forth above. With respect to claims 5 and 7, the Examiner takes the position that the Petruzzi device is capable of meeting the limitations concerning the spacing between the smaller and larger curves. This statement misconstrues the limitations—they are limitations on the distance of each curve from the distal end of its respective tube or element, not on the spacing between the curves. Petruzzi clearly does not show a curve in the outer element within the specified distance from the distal end of that outer element. In fact, the relevant distal portion of the outer element of Petruzzi is clearly straight, and no provision is disclosed by which the relevant distal portion could be bent. Claims 5 and 7 are allowable over Petruzzi for these reasons as well.

With respect to the rejection of these claims, the Examiner further takes the position that Cho teaches rotation of the inner element with respect to the outer element. Note, however, that in the Petruzzi apparatus such rotation would result in an apparatus that would not hit what it was aiming at. The motivation for making such an inoperative device is minimal, at best. Note as well that Cho teaches rotation only with respect to a straight distal segment of an outer tube.

There is in Cho no disclosure of rotation of an inner curved distal portion with respect to an outer curved distal portion. In terms of claim 1, the Cho apparatus is always "in plane" because the distal portion of Cho does not define a single plane—it defines an infinite number of planes. The curved inner element of Cho thus always falls within one of the infinite number of planes defined by the outer tube, so that the inner and outer tube distal portions are always co-planar.

Claims 10-16 are allowable over Petruzzi and Cho for substantially the same reasons set forth above in connection with claims 1-7, and in connection with the discussion of the Sylvanowicz reference.

The Examiner has rejected claims 1-18 under Section 102(e) or, alternatively, Section 103(a) over Cho. Cho does not add any of the features discussed above as missing from Petruzzi. The distal end of the outer tube of Cho is straight, which means that its longitudinal axis defines an infinite number of planes. The inner element of Cho, therefore, even if curved, always falls within one of these infinite number of planes. For example, no matter how the inner element in Cho in rotated, its distal end remains in the same plane as the distal end of the outer catheter tube. This can be seen in the following Figures from Cho:

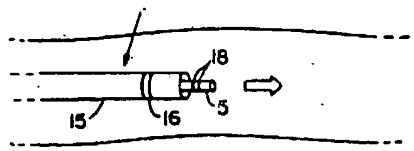


Fig. 5a

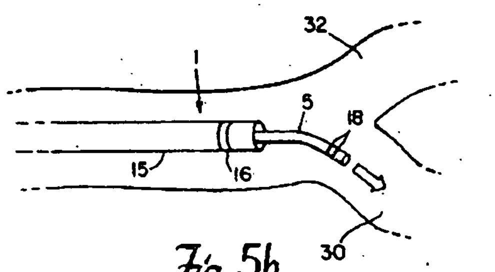


Fig. 5b

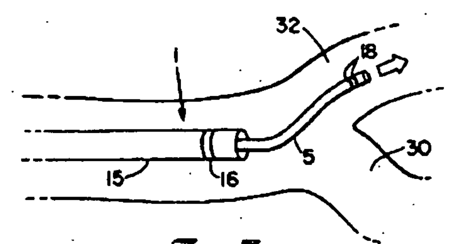


Fig. 5c

Note that in Cho the outer tube is used to point the inner element in the general direction and the inner element is curved so as to move into vessels that are positioned slightly on each side of that general direction. Importantly, if the outer tube in Cho were curved in the manner specified by the present invention, a simple rotation of the inner element would not result in the intubation of the two passages illustrated in Cho. In fact, that operation would be impossible because the inner element would not longer be positioned correctly. What motivation can there possibly be to change the construction of Cho from one that accomplishes its desired purpose to one that is incapable of performing that purpose? Cho is clearly directed to a different problem, and has no teaching whatsoever of the out-of-plane feature resulting from the presently claimed

invention. The only motivation for modifying Cho in this manner is the hindsight provided by the present invention. That is, of course, improper.

Turning specifically to the claims, claims 1 and 10 both require that the outer tube be fixed with its distal end portion in a curve that defines a first plane. If the outer tube of Cho were fixed in such a curve, simple rotation of the inner element of Cho would result in various out-of-plane shapes—none of which would result in intubation of the two vessels shown in Cho. These claims are clearly allowable over this reference.

The remaining claims all depend from either claim 1 or claim 10 and are allowable therewith. In addition, there is no showing in Cho of the specified distance of the curves from the ends of their respective elements (claims 5, 7, 14 and 16). The Examiner takes the position that Cho is capable of meeting the limitations concerning the spacing between the smaller and larger curves, but as pointed out above this is a misreading of the actual limitations. The limitations of these claims (in claims 5 and 7 as filed, and in claims 14 and 16 as amended) relate to how close the curves of each tube/element are to the tip of that particular tube/element—not to the separation between the curves. Moreover, the claimed positioning is not shown in Cho and if it were Cho would not work in the way it describes to accomplish its purpose. These claims are allowable for these reasons as well.

Therefore, claims 1-7 and 10-16 are allowable.

The Examiner has also rejected claims 1-18 under Section 102(b) or, alternatively Section 103(a) over D'Amelio. D'Amelio et al. is fundamentally different from the presently claimed invention. D'Amelio et al. requires four (4) operating cables (pull-wires) 64 to manipulate the flexible end member 60 of a borescope 34 for inspecting a jet engine. The reason for four cables is stated in the following passage from D'Amelio et al.:

"With the cables 64 placed at spaced circumferential locations around the inner surface 66, the distal collar 58 can be moved in as many directions as there are cables. Since there are four cables at equally spaced circumferential locations in the illustrated embodiment, that construction provides movement in four different directions lying in two different intersecting planes."

If D'Amelio et al. were actually performing the presently claimed invention, only one of the pull-wires would be needed (as in the present application). The other three would be superfluous. Yet D'Amelio et al. uses four. D'Amelio et al. is clearly directed to a very different device being used for a very different purpose.

As an aid to understanding the D'Amelio et al. reference, the following chart is provided which sets forth relevant passages from D'Amelio et al. and their relevance, with emphasis added:

Passage from D'Amelio et al.	**Relevance to Present Application**
"A problem arises in using presently available flexible devices for the internal inspection of complex articles of manufacture such as interior regions within jet engines. For example, certain compartments within the engine, such as the aforementioned regions within the burner cans and the turbine, are at present effectively inaccessible to viewing by an inspector. Such inaccessibility is the case	This passage teaches that the D'Amelio et al. device, unlike most medical catheters, is designed to function in an environment "characterized by relatively open spaces and few appropriate supporting surface[s] readily available to guide the objective end of the inspection device." This is in contrast to the shapeable catheter of the present invention. Various shapes have been designed to interact

even with the use of an inspection device such as an endoscope because the articulation of the inspection device requires some sort of guiding surface, such as the interior wall of the colon, to orient and support the inspection device. In contrast to the colon of the human body, a jet engine has **an interior characterized by relatively open spaces and few appropriate supporting surface readily available to guide the objective end of the inspection device**. In addition, presently known endoscope designs, even when used for their originally intended purpose, are not easily able to negotiate all colon configurations without **substantial risk of puncturing the colon wall**." Col. 2, lines 3-22.	with the walls of various human vessels, including out-of-plane shapes. The present invention permits the formation of these shapes in situ, while the D'Amelio et al. reference teaches avoiding the walls. Note that even in the case of colonoscopy, the D'Amelio et al. reference teaches the desirability of avoiding the colon wall. See, col. 2, lines 19-22.
"Additional **problems** with the **known devices** are that the guide tube can **only articulate in two directions**, i.e. in one plane, which makes it very awkward and time consuming to get the distal end thereof in the **proper location** for feeding the viewing scope through the	Teaches the desirability of being in the "center of the burner can" for inspection. Shows that the patent is directed toward positioning the distal end ("get the distal end thereof in the proper location") rather than forming an out-of-plane shape.

crossover tubes. This is generally done by lining up in the plane by which articulation of the distal end thereof is possible and then jumping or jogging the cable around to exactly line it up **so that the viewing scope can be located correctly**. Finally, the known scopes cannot easily accomplish inspections of the louvered section of the burner can or the first stage stationary vanes and first rotor as they **cannot be easily located in the center of the burner can** for ease of such inspection." Col. 3, lines 4-17.	
"The distal end is slidably inserted through a tubular elongated flexible guide member which has an operating head at a near end and a distal collar at a remote end capable of **deflecting in four discrete directions**. The objective assembly of the borescope is capable of deflecting in two discrete directions." Col. 3, lines 31-37.	Talks about deflecting in four discrete directions and two discrete directions. No hint that an out-of-plane shape, as defined in the claims, is desirable or even possible with such a construction. D'Amelio et al. invention is thus directed to maximum flexibility in the placement of the distal end, not its out-of-plane shape.
"The device of the invention provides for a **four-way (two-plane) articulation** of the	Talks about deflection in two different planes with the D'Amelio et al. device, but again

flexible guide tube whereas known devices provide for only a two-way (one-plane) articulation of the guide tube. As with the prior art, the present invention also provides for a two-way (one-plane) articulation of the viewing scope or borescope." Col. 3, lines 60-66	totally fails to realize that one can achieve distal configurations that are out of either of those two planes.
"Since there are four cables at equally spaced circumferential locations in the illustrated embodiment, that construction provides **movement in four different directions** lying in two different intersecting planes." Col. 6, lines 27-31.	Teaches movement in four different directions lying in two different intersecting planes, but again fails to even hint that the distal end can be disposed out of either of those two intersecting planes. D'Amelio contemplates planar movement in either of two selected planes, but not an out-of-plane shape as defined by the claims.
"**Extension and retraction** of the telescoping support member 38, as shown in FIGS. 9A and 9B is effected by rotating knurled nuts 38A AND 38B to grasp and release the internal tubular members in the conventional fashion." Col. 6, lines 35-39	Knurled knobs 38A and 38B are taught as holding against longitudinal movement only.
"However, it will be appreciated that even in	Describes the longitudinally retracted and

the retracted position of the flexible body 42, the objective assembly 46 can still be manipulated to the dotted line positions indicated in FIG. 3A. In its **retracted position**, the objective assembly 46 may typically extend approximately 1.4 to 2.0 inches beyond the distal collar 58 and in the **extended position**, approximately 6 to 8 inches or longer beyond the distal collar 58." Col. 6, lines 57-65	extended positions of the D'Amelio et al. device. Again, no reference to fixing the two parts of the device against rotation.
"The retention spring 68 is preferably fashioned from flat stock so as to occupy minimal space when viewing the tubular member 60 from an end. The retention spring thus serves to retain the operating cables 64 and their surrounding sheaths in their proper respective positions even though **the borescope 34 is twisted relative to the tubular member 60.** Specifically, the retention spring 68 prevents the operating cables 64 from spiraling with the borescope 34 **as the latter is spun inside the tubular member 60**. In the absence	Far from desiring fixing of the borescope of D'Amelio et al. against rotational movement, such rotational movement is desired to accomplish its purpose.

of the retention spring 68, the operating cables 64 would tend to **spin** with the borescope 34 which would not only cause interference between the borescope and the tubular member 60, but also would cause unreasonable and unnecessary wear on the parts." Col. 7, lines 13-25.	
"These differences include the capability of the guide member 36 having four-way, that is, two-plane articulation." Col. 7, lines 30-32.	"Reference to "two-plane articulation" but no clue that out-of-plane shaping is possible.
"In a typical maneuver, as illustrated in FIG. 13, while the objective assembly 46 is viewing the liner of the burner can 74 opposite the igniter port 76, the distal collar 58 is articulated by means of the actuating knobs 62 and 63 to enable the objective assembly 46 to locate a crossover tube 78 between the adjacent burner cans 74. With continued manipulation by the operator of the inspection system 30, the distal collar 58 is moved closer to the crossover tube 78 as illustrated in FIG. 14 **while keeping the tube 78 in the center of view** of the objective	"Illustrates how the D'Amelio et al. device relies solely on optical feedback to place the device properly. Also illustrates that the location, not the shape, of the distal end is the only thing of interest to D'Amelio et al.

assembly 46."	
"During this entire procedure, areas of interest within the burner cans can be inspected by articulating the objective assembly 46 and the distal collar 58, feeding the system 30 to an extreme end of a burner can, then extending the objective assembly 46. The inspection itself is performed as the system 30 is withdrawn from each burner can. To inspect an area around a crossover tube through which the objective assembly 46 and distal collar 58 are inserted is generally illustrated in FIG. 19. For this view, the objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 28-39	Again describes operation of the D'Amelio et al. device, and in particular teaches (with respect to Fig. 19) that the inner and outer elements "must articulate in the same plane." This is a clear teaching away from the present invention which requires an out-of-plane shape.
"There are numerous advantages inherent in the present invention over the known devices. In the first place, the four-way articulation of the steerable flexible guide member 36 allows a quicker, more **precise positioning** of its distal end before the objective assembly 46 is extended. This is important because of the	D'Amelio et al. is teaching positioning of the distal end—not shaping. D'Amelio et al. is indifferent to the shape of the device. Position is all that matters in the D'Amelio et al. patent.

different positional locations between the igniter port 76 and the crossover tubes 78 and other elements to be inspected by the device." Col. 8, lines 40-48.	
"This is done by placing the distal end of a flexible guide member 36 **in the center of the burner can** 74 as illustrated by dotted lines in FIG. 1. The invention, by virtue of its four-way articulation, permits the distal collar 58 to be easily **placed in the center of the burner can** and then to **spin or rotate** the objective assembly 46, which is positioned near the louvered area 80, in a 360 degree arc so as to inspect each one of the louvers. This easily performed operation contrasts with the prior art constructions which are restricted by a two-way articulation at the end of their equivalent of the tubular member 60. Such prior art devices cannot be **positioned** very easily in the center of a burner can but must be **located in several positions** in order to inspect all of the louvers around the outside of the burner can."	Teaches placing the end of the outer element in the center of the burner can (again placement only). Also teaches free rotation of the inner element with respect to the outer element (not rotational fixing). Articulation of the outer member in four directions (apparently never at the same time) is used solely to facilitate the placement of the end of the device in the center of the burner can. At that point, the inner member is spun or rotated to observe all the louvers. This should be contrasted with applicant's out-of-plane feature, which would not provide this functionality. A catheter with an out-of-plane distal tip could not, by rotation of the inner element with respect to the outer, result in observation of the various louvers. This difference is fundamental. D'Amelio et al. is interested in positioning—the present

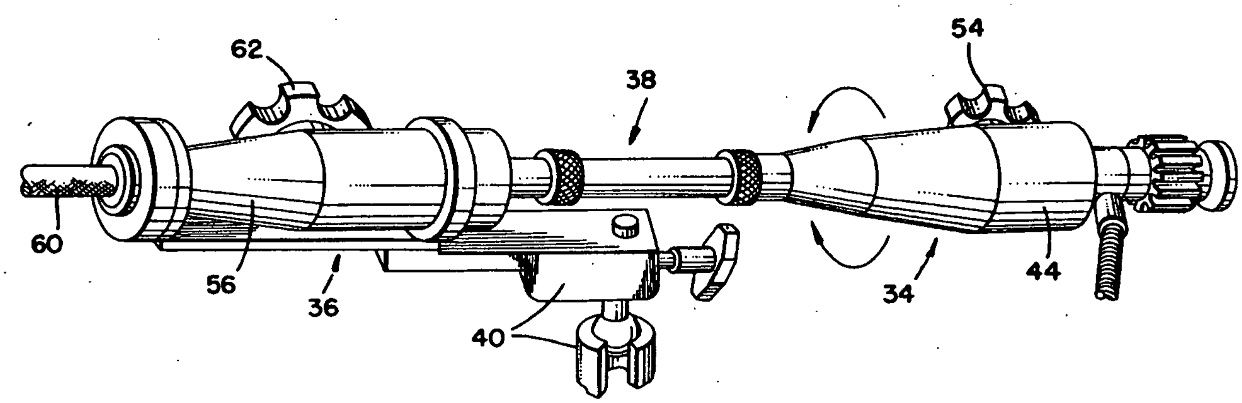
Col. 8, line 55 to col. 9, line 2.	invention is directed to forming out-of-plane shapes.
"It is also noteworthy that the first stage of the jet engine 32 can be much more easily viewed by the invention. This is depicted in FIG. 21 which illustrates the distal collar 58 being **precisely located within the burner can** next to the fixed guide vanes 82 of the first stage of the jet engine 32. In this manner, the objective assembly 46 can be fed through the vanes in a precise manner and displaced accurately adjacent the first stage rotor 84. The rotor can then be turned by hand for complete inspection by the system 30. While the prior art can theoretically accomplish this end result, the fact is that in order to inspect the rotor 84 and the fixed guide vanes 82, the objective assembly 46 must repositioned several times because of the awkwardness in positioning it in the first place. This awkwardness results from the limited two way articulation system previously employed. Thus, the known	Teaches positioning in the center of the burner can for yet another inspection operation.

inspection systems must work around the area to be inspected with several positions for the end of the guide tube. In contrast, the invention merely requires that the distal collar 58 be set **near the center of the burner can** so that when the objective assembly 46 of the borescope 34 is fully extended, it will be in the precise position to get into the rotor area." Col. 9, lines 3-26.	
"Also, it should be noted that when the control head 44 is moved relative to the operating head 56 and **spun or rotated** in a concentric manner with the tubular member 60, the proximal end thereof is relatively linear and rigid. Another element of the construction of the present invention which adds considerably to the reliability of the invention is the provision of the retention spring 68 which eliminates potential problems of the operating cables 64 twisting with the flexible body 42 as the latter is **spun or rotated** inside the tubular member 60." Col. 9, lines 46-57.	Again teaches free rotation of the inner element with respect to the outer element—not rotational fixing.

Preliminarily, it should be noted that there is nothing in D'Amelio et al. which would motivate one of ordinary skill in the art to make any modifications to the D'Amelio et al. apparatus whatsoever. The apparatus appears to adequately solve the problems at hand, and there are no hints of any deficiencies in D'Amelio et al. Moreover, the Examiner has not pointed to anything in other prior art which would suggest making any modifications to D'Amelio et al.

Turning to the D'Amelio et al. disclosure itself, in addition to Figs. 13-16 and 19, Fig. 3 is set out for convenience below. Fig. 3 gives an overview of the two major components of the D'Amelio et al. device.

FIG. 3.



As can be seen from Fig. 3, the D'Amelio et al. device includes an inner portion (borescope 34) which is designed to be rotatable (as indicated by the arrows) with respect to an outer guide member 36. Figs. 13-16 and 19, on the other hand, illustrate various ways in which the D'Amelio et al. device is used.

FIG. 13.

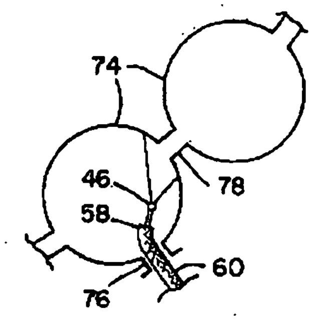


FIG. 14.

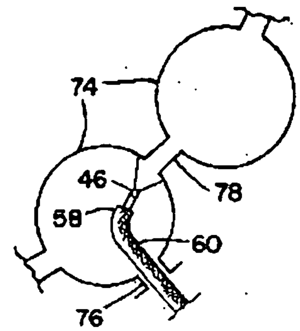


FIG. 15.

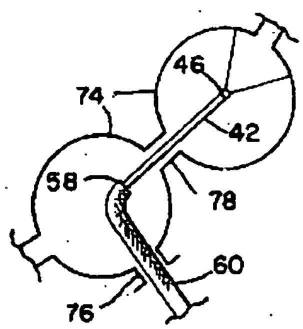


FIG. 16.

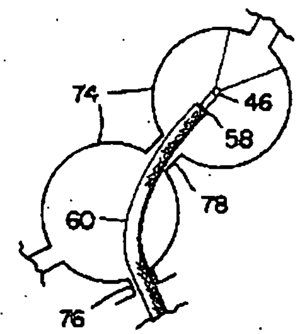
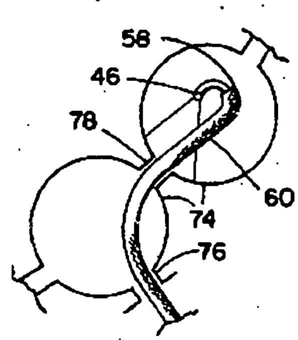


FIG. 19.



The claimed inventions are very different from D'Amelio et al.. D'Amelio et al. is indifferent to the shapes formed by the apparatus since the D'Amelio device has direct information as to the direction in which the device is pointing. (The entire purpose of D'Amelio

et al. is to point an optical inspection apparatus toward the area of interest.) Any duplication of the present invention, forming out-of-plane shapes, therefore, is not only accidental or unwitting, it would be purely unintentional.

Claim 1, as discussed above, requires the distal end portions of the inner element and outer catheter tube to be out-of-plane with respect to each other. This feature is particularly useful in positioning and anchoring a catheter in locations where it is wedged against a vessel wall (as is commonly done with conventional catheters). D'Amelio et al., on the other hand, is attempting to stay away from the walls of the object under examination, and specifically desires to stay in the center of the can of the jet engine being examined. The D'Amelio et al. invention is described in the context of relatively open spaces through which the examining device moves (see references in the table above to "relatively open spaces" from col. 2, lines 3-22, for example), which is very different from the environment in which the present invention is used.

Importantly, examination of Figs. 13-19 of D'Amelio et al. clearly reveals that the distal portions (as defined) are planar, not "out of plane". Note specifically that with respect to Fig. 19, D'Amelio et al. expressly teaches that "objective assembly 46 **must articulate in the same plane** as the guide member 36." Col. 8, lines 37-39. Claims 1 and 10 are allowable over this reference for essentially the same reasons as they are allowable over the other references discussed above.

The dependant claims, claims 2-7 and 11-16, are allowable along with the independent claims. In addition, claims 6 and 15 are both directed to the feature of one curved element being approximately ninety degrees out of plane with respect to the other curved element. D'Amelio et al. does not teach out of plane in general, and certainly does not suggest that such a angle could be achieved or would be desirable.

Moreover, claims 2 and 11 provide that the inner medical element is proximally fixed against rotation with respect to the catheter tube. In the Office action, the Examiner takes the position that this is accomplished in D'Amelio et al. The Examiner is incorrect. D'Amelio et al. teaches longitudinal fixing, and specifically teaches the desirability of **allowing the inner element to rotate freely with respect to the outer tube**. In fact, fixing the inner element against rotation would be directly contrary to the oft-stated and consistent intent of the disclosure of D'Amelio et al. to freely rotate to inspect the components of the jet engine. D'Amelio et al. teaches neither the structure for rotationally fixing, nor the step of rotationally fixing. Since D'Amelio specifically teaches scanning the interior surface of the jet engine, it is highly unlikely that it ever anticipates fixing the inner element in any one rotational position. In fact, considering the fact that D'Amelio is directed to an inspection device, it is unlikely that such fixing in a particular rotational position would ever be desired. Rather, it would appear to be undesirable. Fixing against rotation, as required by these claims, is not shown or suggested by D'Amelio. Nor is it inherent in D'Amelio since it is not necessarily present. Claims 2 and 11 are allowable for these reasons as well.

The Examiner takes the position that "the D'Amelio device is capable of meeting the limitations concerning the spacing between the smaller and larger curves." These limitations are found in claims 5, 7, 14, and 16. As has been pointed out above, the significant limitations (in claims 5 and 7 as filed and in claims 14 and 16 as amended) are not directed to the spacing between the curves, but rather to the maximum spacing of each curve from the tip of its respective element.

For all these reasons, claims 1-7 and 10-16 are allowable over the cited art.

New claims 19-22 are similarly allowable over this art. Claim 19 is specifically directed to a method of forming a combination catheter, having an outer tube with a curved distal portion whose longitudinal axis defines a first plane, into a shape in which the distal end of the combination catheter as a whole is disposed substantially out of the first plane. As discussed above in connection with the other independent claims, the art does not show or suggest this feature. D'Amelio, in fact, teaches against it.

Claims 20-22 depend from claim 19 and are allowable therewith. In addition, claim 20 further specifies that the combination catheter is positioned in a desired position and used in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane. This claim explicitly rules out the transitory configuration that the Examiner finds in Sylvanowicz.

Claim 21 depends from claim 20 and further requires reforming the distal end of the combination catheter into a substantially different shape. Claim 22 further depends from claim 21 and specifies that the combination catheter is used in a medical procedure while the distal end of the combination catheter is in the reformed shape. None of these features is found in the prior art in combination with the "out-of-plane" shape of the present invention.

Claims 19-22 are allowable for these reasons.

Applicant reiterates his offer to interview this case to demonstrate the models and videotape in the Examiner's possession and to discuss allowable subject matter.

Conclusion

In summary, the claims (particularly as amended) are directed to a combination catheter with an out-of-plane shape (achieved by two curved elements) that is not merely transitory, but rather is deliberately formed and maintained so that either the inner medical element or the

catheter tube can be used for a medical purpose. This feature is absolutely fundamental, and is irrefutably only found in the present disclosure. The out-of-plane feature provides shapes for specific purposes, such as anchorage or wedging of the catheter in a desired location, which heretofore have required specially designed preformed catheter shapes to achieve, as described in detail in the passages from the present specification below.

The prior art is very different. Sylvanowicz points to the left or right coronary arteries and extends an inner catheter toward the ostia using respective planar shapes with one functionally straight element and one curved element (Syl., col. 7, ll. 46-52). Petruzzi points to the ampulla of Vater and a catheter is extended from the distal tip in the plane of sight into the common bile duct, using one functionally straight element and one curved element (Pet., Col. 1, ll. 59-62). The catheter in Cho is pointed in a right-hand lateral or left-hand lateral direction in a single plane of a body cavity with one straight and one curved element (Cho, col. 4, ll. 60-68, col. 5, ll. 1-9). D'Amelio points backward to inspect in Fig. 19, with two curved elements that must be in plane. In D'Amelio, either element could have more or less curvature than is shown in Fig. 19—the exact shape of the combination is unknown and unknowable in D'Amelio, the only feature of importance being whether the desired area of inspection is in view. This is very different from the present invention where the goal is the out-of-plane shape, not the direction of pointing. (D'Am., col. 8, ll. 34-39).

Shaping, particularly to fix location—not pointing, aiming, guiding, or steering—is the clear distinction of the present invention over the prior art. This distinction, and the invention itself, is fully and clearly articulated in the following passages from the present specification:

> "Catheter 31 is not simply a steerable catheter, but also one which may be custom curved and recurved by the user to select each branch vessel. Page 8, lines 10-11.

"As will become apparent in view of the following disclosure, manipulation of catheter 31 results in mimicking virtually any simple or complex curved configuration of selective arterial catheter shape imaginable while the catheter is disposed in the patient. Page 8, lines 14-16.

"Tip reorientation, the goal of most prior devices which have addressed the problem, is only half of what is needed to make a truly workable universal catheter. Numerous catheter configurations have been conceived not only to reorient the tip properly for selection of branch vessels, but also to provide anchorage of the catheter against the aortic wall. Page 1, lines 24-27.

"These complex configurations, therefore, evolved not only to orient the tip properly, but also to wedge the catheter securely in the branch vessel. Other devices which simply modify the distal catheter curve may aid in tip orientation for vessel selection, but fail to provide the anchorage which is necessary to prevent catheter dislodgement." Page 2, lines 6-9.

All the prior art except Cho points with a proximal element and moves the distal element to perform a medical procedure—the proximal and distal elements are not "fixed" together, rather each performs its own function separately. Cho fixes the elements together and then uses the catheter as a unit, but Cho uses a functionally straight element and a curved element which are always in plane. That is, the art in general points with one (usually straight) element and moves the other to carry out a medical procedure. The presently claimed invention forms shapes with two curved elements and uses the formed shape of the combination to carry out a medical procedure.

Thus, the presently claimed invention constitutes a new, nonobvious and useful medical device and method—a true invention. This invention is not shown or suggested in the prior art, but is irrefutably set forth in applicant's disclosure.

Favorable reconsideration and a Notice of Allowability of claims 1-22 is solicited.

Respectfully submitted,

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